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Dated: 9-10-04 Signature: Maura A. Gallagher
(Maura A. Gallagher)

Docket No.: MTY-P04-006
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gellman et al.

Application No.: 10/774842

Confirmation No.: 1110

Filed: February 9, 2004

Art Unit: N/A

For: DEVICES FOR MINIMALLY INVASIVE
PELVIC SURGERY

Examiner: Not Yet Assigned

**PETITION TO MAKE SPECIAL
UNDER 37 CFR 1.102(d)**

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Submitted herewith is a Petition to Make Special the above-identified patent application.

Attorneys for Applicants hereby state that a preexamination search was conducted. Copies of known references related to the subject matter have been submitted to the PTO attached to Information Disclosure Statement filed on September 10, 2004, and a Preliminary Amendment has also been submitted to the PTO on September 10, 2004, copies of both filings are attached hereto for convenience.

The following art is known to Attorneys for Applicants and may be related to subject matter of the pending claims as presented in the Preliminary Amendment filed on September 10, 2004 for the present application: U.S. Patent No. 4,798,193; U.S. Patent No. 4,824,435; U.S. Patent No. 4,896,668; U.S. Patent No. 5,064,435; U.S. Patent No. 5,112,344; U.S. Patent No. 5,152,749; U.S. Patent No. 5,234,457; U.S. Patent No. 5,334,185; U.S. Patent No. 5,337,736; U.S. Patent No. 5,354,292; U.S. Patent No. 5,611,515; Norris et al., Journal of Endourology,

Volume 10, page 227-230, June 1996; and Petros and Ulmsten, Scandinavian Journal of Urology and Nephrology Supplement 153, 1993, which are summarized below.

Additionally, we did the following searches:

1. We studied the file history of U.S. Patent No. 6,491,703 and identified two U.S. patents cited therein—U.S. Patent No. 5,250,033 and U.S. Patent No. 5,368,595—that may be related to the subject matter of the pending claims as presented in the Preliminary Amendment filed on September 10, 2004 for the present application. We also electronically searched via the Delphion Web site the hyper links to the references cited in and the references citing these two U.S. patents and identified the following related art: U.S. Patent No. 3,472,232; U.S. Patent No. 3,763,860; U.S. Patent No. 4,983,168; U.S. Patent No. 5,167,634; U.S. Patent No. 5,409,469; U.S. Patent No. 5,647,857; U.S. Patent No. 5,935,122; and DE 43 34 419 A1, which are summarized below.

2. We also conducted full-text keyword searches in all of Delphion's databases (i.e., U.S. patents, U.S. patent applications, European patents, European patent applications, WIPO/PCT international patent applications, German databases including granted patents and pending applications, Japanese abstracts, and INPADOC).

- 1) We used the following search terms: ((mesh or sling or tape) and (pouch or envelope or sleeve or sheath) and urinary). We reviewed the 189 results from this search and identified 10 additional relevant references: U.S. Patent No. 5,417,226; U.S. Patent No. 5,562,717; EP 0417189 B1; EP 0506920 B1; EP 0628288 B1; EP 0831751 B1; EP 1321111 A2; WO96/01597; WO 96/34587; and WO 96/39227, which are summarized below.
- 2) We also used the following search terms: ((mesh or sling or tape) and (pouch or envelope or sleeve or sheath) and (medical or surgical)) and did not find any additional relevant references.
- 3) We also used the following search terms: ((mesh or sling or tape) within five words of (pouch or sleeve or sheath)) and limited to U.S. classes 128/600/601

/602/604/606/607/623 or limited to IPC: A61. We did not identify any additional relevant references.

With respect to the subject matter of the references, Applicants submit the following:

1. U.S. Patent No. 3,472,232 – This reference generally relates to a catheter insertion device. In particular, as illustrated in Figure 1 and Figure 7, the catheter 14 is received within the cannular 12. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.
2. U.S. Patent No. 3,763,860 – This reference generally relates to a laparoscopy instrument and a method for suturing and ligation. In particular, as noted in Figure 2, a sheath 14 covers a stem 11 and the stem 11 is to be removed from the body while the sheath 14 is left within. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.
3. U.S. Patent No. 4,798,193 – This reference generally relates to a protective sheath instrument carrier. In particular, as shown in Figure 7, the instrument is introduced into the sheath through the handle 12. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.
4. U.S. Patent No. 4,824,435 – This reference generally relates to an instrument guidance system. As shown in particular in Figures 1 and 3, the instrument comprises a primary guide wire 14 and a secondary guide wire 12. As shown in Figure 2, the primary guide wire 14 is inserted into the lumen of the tube 16. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.
5. U.S. Patent No. 4,896,668 – This reference generally relates to a plate set for osteofixation equipped to suture strands. The plate set is for securing a patient's rib cage following surgery and for protecting internal organs during subsequent surgical procedures. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

6. U.S. Patent No. 4,983,168 – This reference generally relates to a medical-layered peel-away sheath and the methods of using the sheath. In particular, as shown in Figure 1, a catheter tube 16 is inserted into the target body site through the hollow interior of the peel-away sheath 10. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

7. U.S. Patent No. 5,064,435 – This reference generally relates to self-expanding prosthesis having stable axial length. In particular, as shown in Figure 1, stent 16 is in a relaxed condition. As shown in Figures 2 and 3, the stent is elastically deformed and maintained in a radially reduced configuration by a pliable sheath 38 surrounding the stent 16. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

8. U.S. Patent No. 5,112,344 – This reference generally relates to methods and the surgical instruments for treating female incontinence comprising looping a filamentary element 19 between the wall of the vagina 16 and rectus abdomenis sheath in the interior wall of the abdomen, whereby it passes to each side of the urethra 20 into the correct spatial relationship to the pubis 17. The surgical instrument comprises a tubular shaft 11 having a handle 12 at one end and carried toward its other end a flexible needle element 13 slidably receivable in the shaft 11 and adapted at one end to receive a filamentary element 19 and having an enlarged profiled portion 15 at its other end, whereby when the needle element 13 is received in the shaft 11, the other end of the needle element 13 defines a convergent surface of the other end of the shaft 11 and the one end of the needle element 13 is exposed at one end of the shaft 11. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

9. U.S. Patent No. 5,152,749 – This reference generally relates to a surgical apparatus for the placement of an instrument within a body cavity which comprises a placement device including an elongated element with an exposable tissue piercing tip, a first coupler adjacent to the tip and a structure for selectively exposing the tip and an elongated instrument for placement including a second coupler adapted to be coupled to the first coupler to effect an end-to-end coupling of the device and the instrument whereby the instrument is positioned within the body cavity. This reference also discloses a method for placement of a supra pubic instrument. This

reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

10. U.S. Patent No. 5,167,634 – This reference generally relates to a peelable sheath with hub connector. The peelable sheath includes a sheath formed of a flexible tube having a pair of separation lines arranged longitudinally on radially opposite sides of the tube to form a pair of peelable sheath portions and a hub connector bonded to the proximal end of the sheath. In particular, as shown in Figure 1, the peelable sheath 10 generally comprises a sheath 12, a pair of wings 14 and a hub connector 16. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

11. U.S. Patent No. 5,234,457 – This reference generally relates to a stent assembly, delivery system and the method of manufacture therefor. In particular, Figure 1 shows the stent 10 and Figure 2 shows the stent 10 being compacted into a stent assembly 20. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

12. U.S. Patent No. 5,250,033 – This reference generally relates to a peel-away introducer sheath having proximal fitting. The peel-away introducer sheath includes a tube sheath having a splittable handle at its proximal end. In particular, as shown in Figure 2, the introducer sheath 10 comprises a sheath tube probe and a handle 18 including a first tab 36 and a second tab 38. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

13. U.S. Patent No. 5,334,185 – This reference generally relates to a surgical apparatus for the placement of an instrument within a body cavity. As disclosed in this reference, the instrument preferably is a suprapubic instrument for placement within a bladder. In particular, Figure 1 shows a suprapubic instrument placement device 10 includes a handle 12 with the central slot 14 therein. The instrument further comprises a rigid needle 20. Figures 11A to 11C show the placement of the stent 100 for coupling of the kidney 112 and the bladder 122. The placement system comprises a guide wire 102 and a cystoscope 124. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

14. U.S. Patent No. 5,337,736 – This reference generally relates to a retraction method and apparatus therefor. The method and apparatus are used for in laparoscopic surgery in the body cavity for moving an internal organ or vessel which interferes with the surgery and then maintaining it there apart from a laparoscopic port. In particular, Figure 1 shows a sling 10 of the invention comprising a web or a membrane 12 with one or more lines or leads 14, 16 attached one on each end of the sling 10. Further, the forceps 128 is shown in Figure 8 and Figure 9 to grip one of the leads 130, 132 of a sling 134. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

15. U.S. Patent No. 5,354,292 – This reference generally relates to a surgical device including a specially adapted surgical mesh and a mechanical means for attaching the surgical mesh to the pubic bone. The surgical mesh is mechanically attached to the pubic bone by an orthopedic scope and the peripheral margins of the mesh are either sutured or stapled to the appropriate anatomical structures. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

16. U.S. Patent No. 5,368,595 – This reference generally relates to an implant assist apparatus. In particular, Figure 1A shows a braided tubular ligament prosthesis 21 and a substantially leaner cannular 23 enclosing a portion of the prosthesis 21. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

17. U.S. Patent No. 5,409,469 – This reference generally relates to an introducer system having kink-resistant splittable sheaths. As shown in Figure 16, the kink-resistant section 70 has a series of pleats 72. The pleats 72 permit kink-resistant sections 70 to bend more readily within a body 10 without the formation of kinks as shown in Figure 17. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

18. U.S. Patent No. 5,417,226 – This reference generally relates to a female anti-incontinence device including two flexible disks attached to a flexible stem. The device is inserted into the urethra so that the larger disk occludes the bladder neck during sudden tensing of the abdominal muscles, while the smaller disk remains outside the urethra and prevents migration of the device into the bladder. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

19. U.S. Patent No. 5,562,717 – This reference generally relates to electrical stimulation for the treatment of neuromuscular disorders, in particular incontinence. As shown in Figure 27, the insertable electrode comprises an inner core formed by material such as a form or paper/cotton fiber 100 and an outer conductive sheath 101 of knitted or woven conductive fiber. For example, stainless steel fiber or metalized plastic fiber. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

20. U.S. Patent No. 5,611,515 – This reference generally relates to the surgical treatment of a stress urinary incontinence. Figure 5 shows a cross-sectional view of a suture passer. This reference also teaches a surgical drill guide for drilling a hole in the pubic bone for anchoring sutures. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

21. U.S. Patent No. 5,647,857 – This reference generally relates to a sheath holding a device against a balloon catheter for delivery in the lumen of a patient. The device can be a stent or graft combination. As shown in Figure 1, the graft delivery system includes a multi-lumen catheter 60 and a sheath 10 holding the stent and graft combination 56 tightly onto the catheter 60. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

22. U.S. Patent No. 5,935,122 – The reference generally relates to a sheath assembly for use in introducing a catheter or other medical instrument into a vessel in the body of a patient. The sheath assembly includes an outer tubular member and an inner tubular member with a conically shaped cap at its distal end. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

23. DE 43 34 419 A1 – This reference generally relates to a surgical aid 1 as shown in Figure 1. The surgical aid 1 has a shaft part 6 with a handle 7 and, at the distal end area of the shaft part, a holding device 8 for at least one surgical instrument 2. A protective covering is also provided which is formed by a sleeve 9 and which is in the covering position covers the pointed end or sharp ends of the surgical instruments 2. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

24. EP 0 417 189 B1 – This reference relates to the field of catheters. In particular, the reference relates to catheters which are adapted to be inserted into the urethral lumen to alleviate obstructive prostatism, a condition quite common in males over the age of 50. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

25. EP 0 506 920 B1 – This reference generally relates to urinary control. In particular, as shown in Figure 1, the urinary control includes a urine tube 12 in which a valve 14 is connected. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

26. EP 0 628 288 B1 – This reference teaches a device that provides a precise controlled positioning of a treatment stylet in a tissue targeted for treatment destruction or sampling from a catheter positioned in the vicinity of the target tissue. The term “stylet” is defined to include both solid and hollow probes which are adapted to be passed from a catheter port through normal tissue to target tissues. In particular, Figure 7 shows an electrode 32 at least partially covered by a sleeve 30. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

27. EP 0 831 751 B1 – This reference generally relates to a urethral cap for alleviating urinary incontinence. This reference teaches that the urethral cap can be packaged in a surrounding clear plastic container or envelope to maintain the cleanliness of the cap prior to usage. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

28. EP 1 321 111 A2 – This reference generally relates to a self-cleansing bladder drainage device. The reference teaches that it may prove efficacious to coat the drain member with hydrogel to render it more soft and lubricious to aid in insertion into the urethra. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

29. WO 96/01597 – This reference generally relates to a vessel occlusive apparatus for reversibly occluding a fluid combing vessel in a human or animal. As shown in Figure 5A and 5B, the cable member 58 and the sheath 63 are attached proximate at distal end to a pubic bone

structure 109 in the body on one side of the urethra 64. The sheath 63 is connect to the conduit 60 proximate to a proximal end. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

30. WO 96/34587 – As shown in the representative figure, this reference teaches a urethral plug 1 comprising a cooperating shaft 12 and a balloon 18. Figure 7 shows a package containing a sterile urethral plug 1. The partially opened package 52 contains the exposed plug 1 and the package 52 can serve as a protective sheath, thereby preventing human contact with the sterile plug 1 while attaching the applicator 40. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

31. WO 96/39227 – This reference generally relates to an intra-urethral catheter shaft 32 comprising a plurality of lumens extending between the first end and the second end of the shaft 32. In particular, as shown in Figure 3, a multi-lumen shaft 32 includes several lumens and a protective sheath 71 covering outer surface 52 of the catheter shaft 32. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

32. Norris et al., Journal of Endourology, Volume 10, page 227-230, June 1996 – This reference is entitled “Use of Synthetic Material in Sling Surgery; A Minimally Invasive Approach.” This reference teaches affixing a rectangular patch as a sling to allow suspension of the bladder neck by securing sutures to the mobilized edge of the periurethral fascia and the pubourethral ligament with a running stitch. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

33. Petros and Ulmsten, Scandanavian Journal of Urology and Nephrology Supplement 153; 1993 – This reference is entitled “Integral Theory and Its Method for the Diagnosis and Management of Female Urinary Incontinence.” This reference teaches, in Part IV, surgical applications of the theory on female urinary incontinence. The surgical applications disclosed are pre-1993 intravaginal slingplasty procedures and the free graft procedures. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

Accordingly, Applicants request that this Petition to Make Special be granted and the application undergo accelerated examination.

Please charge our Deposit Account No. 18-1945 in the amount of \$130.00 covering the fee set forth in 37 CFR 1.17(h). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. MIY-P04-006. A duplicate copy of this paper is enclosed.

Dated: September 10, 2004

Respectfully submitted,

By 
Agnes S. Lee

Registration No.: 46,862
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant

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FEE TRANSMITTAL
for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 130.00)

Complete if Known

| | |
|----------------------|------------------|
| Application Number | 10/774842 |
| Filing Date | February 9, 2004 |
| First Named Inventor | Barry N. Gellman |
| Examiner Name | Not Yet Assigned |
| Art Unit | N/A |
| Attorney Docket No. | MIY-P04-006 |

METHOD OF PAYMENT (check all that apply)

Check Credit Card Money Order Other None

Deposit Account:

Deposit Account Number 18-1945

Deposit Account Name Ropes & Gray LLP

The Director is authorized to: (check all that apply)

- Charge fee(s) indicated below Credit any overpayments
- Charge any additional fee(s) or any underpayment of fee(s)
- Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

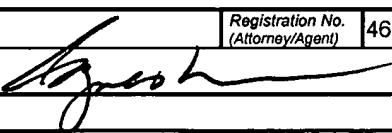
FEE CALCULATION (continued)**3. ADDITIONAL FEES**

| Large Entity | Small Entity | Fee Description | Fee Paid |
|---|---------------|--|----------|
| Fee Code (\$) | Fee Code (\$) | Fee Description | |
| 1001 770 | 2001 385 | Utility filing fee | |
| 1002 340 | 2002 170 | Design filing fee | |
| 1003 530 | 2003 265 | Plant filing fee | |
| 1004 770 | 2004 385 | Reissue filing fee | |
| 1005 160 | 2005 80 | Provisional filing fee | |
| SUBTOTAL (1) (\$) | | 0.00 | |
| 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE | | | |
| Total Claims | -20** = | Extra Fee from Claims below | Fee Paid |
| Independent Claims | -3*** = | | |
| Multiple Dependent | | | |
| Large Entity Small Entity | | | |
| Fee Code (\$) | Fee Code (\$) | Fee Description | |
| 1202 18 | 2202 9 | Claims in excess of 20 | |
| 1201 86 | 2201 43 | Independent claims in excess of 3 | |
| 1203 290 | 2203 145 | Multiple dependent claim, if not paid | |
| 1204 86 | 2204 43 | ** Reissue independent claims over original patent | |
| 1205 18 | 2205 9 | ** Reissue claims in excess of 20 and over original patent | |
| SUBTOTAL (2) (\$) | | 0.00 | |
| *Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$) 130.00 | | | |

**or number previously paid, if greater; For Reissues, see above

SUBMITTED BY

(Complete if applicable)

| | | | | | |
|-------------------|---|--------------------------------------|--------|-----------|--------------------|
| Name (Print/Type) | Agnes S. Lee | Registration No. (Attorney/Agent) | 46,862 | Telephone | (617) 951-7794 |
| Signature |  | | | Date | September 10, 2004 |

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 9-10-04

Signature:  (Maura A. Gallagher)